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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/682,359

10/09/2003

Richard A. Terwilliger

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EXAMINER

GILBERT, SAMUEL G

ART UNIT

PAPER NUMBER

3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/682,359

Applicant(s)

TERWILLIGER ET AL.

Examiner

Samuel G. Gilbert

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,16,20-25,26,28,30-34,43 and 47 is/are rejected.
- 7) ☒ Claim(s) 3,14,15,17-19,27,29,35-42,44-46 and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/18/2004; 2/3/2005</u> .                                     | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 3/18/2004 and 2/3/2005 have been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-13 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 - "the measuring board" lacks antecedent basis. It is unclear if the board is the same board as set forth in claim 1.

Claim 9 - it is unclear with respect to what structure the board extends when it is pulled on.

Claim 11 - if the board is slidably extendable with respect to the envelope, claim 9, how can the board be prevented from advancing beyond the mouth of the envelope.

Claim 21 - it is unclear if the step of sterilizing the pouch will sterilize the apparatus inside the pouch, which appears to be required from the language set forth in the preamble.

Claim 23 - the preamble calls for a method of implanting a plurality of seed strand implants while the body of the claim does not provide the method steps of implanting a plurality of seed strands.

Claim 24 - it is unclear if the step of sterilizing the pouch will sterilize the apparatus inside the pouch, which appears to be required from the language set forth in the preamble.

### ***Claim Objections***

Claims 18, 43 and 45 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 18, 43 and 45 - the claims include only method steps which do not further limit the apparatus claim from which they depend.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 8 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fairbanks et al (5,311,813).

Claim 1 - element -86- is a carrier, as shown in figure 4, element -12- is a measuring and cutting board and element 16 is a shielding envelope, column 2, lines 31-40.

Claim 4 - the system is adapted to be sterilized with ethylene oxide gas.

Claim 8 - when the board is inside the carrier the board may slide, therefore the examiner is considering the board and carrier to be slidably connected.

Claim 20 - element -86- is adapted to carry the entire prescription requirement of one patient, which appears to be broad enough to include only a single piece of paper with a prescription written on it.

Claims 1, 2, 4, 5, 16, 20, 25, 28, 30-32, 43 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Pedersen et al (6,639,237).

Claim 1 - device -300- is a seed strand carrier, staging area -32- is a cutting and measuring board, and body -12- and lid -14- form an envelope.

Claim 2 - elements -302- are a plurality of adjacent tubes.

Claim 4 - the system is adapted to be sterilized using Ethylene Oxide gas.

Claim 5 - the pieces have a lead lining, column 7, lines 22-24.

Claim 16 - the seeds remain shielded until the user retrieves each strand.

Claim 20 - the system is adapted as claimed because the applicant has not set forth any specific structure that is different from Pedersen.

Claim 25 - device -300- is a seed strand carrier, seed strands are shown in elements -84- and -86- in figure 3, staging area -32- is a cutting and measuring board, and body -12- and lid -14- form an envelope.

Claim 28 - device -300- is slidable connected to staging area -32-.

Claim 30 - apertures -302- are adapted to carry the material as claimed.

Claim 31 - the apparatus is adapted to be sterilized as claimed.

Claim 32 - the pieces have a lead lining, column 7, lines 22-24.

Claim 43 - the seeds may remain shielded if the user removes only one seed holder at a time from element -300- housed in the element -34-.

Claim 47 - the apparatus is adapted as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 26, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al (6,639,237).

Pedersen et al sets forth apparatus as claimed including a lead lining, as set forth above. However, the thickness of the lead lining is not set forth. It is old and well

known in the medical arts that the effectiveness of a lead lining is at least partially determined by the thickness of the layer of lead. Further, the thickness is generally determined after the specific type of material to be transported is decided. For example the thickness of lead need to shield beta radiation would be thinner than that required for gamma radiation. In the absence of showing any criticality in the exact thickness of the lead lining the selection of any specific thickness is of no patentable significance and generally considered an ordinary design expedient.

Claim 23 - spacing material or spacers are old and well known in the brachytherapy arts, therefore the examiner is taking official notice that such spacers exist. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to include spacers with the seeds in the staging and sterilization device as taught by Pedersen et al to provide the ability of the user to properly space the seeds as they are implanted as is well known in the brachytherapy art.

### ***Allowable Subject Matter***

Claims 21-24 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 9-13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 3, 14, 15, 17-19, 27, 29, 35-42, 44-46, and 48 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents and Patent Application Publications 6,989,543; 6,472,675; 2,265,680, 2,747,103; 5,322,499; and 2004/0068157 teach related brachytherapy apparatus.

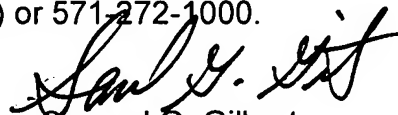
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel G. Gilbert  
Primary Examiner  
Art Unit 3735

sgg